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Translation

PCT/JP2003/006988

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 09559	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/006988	International filing date (*day/month/year*) 03 June 2003 (03.06.2003)	Priority date (*day/month/year*) 03 June 2002 (03.06.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 31/517, 31/519, 31/5377, A61P 9/10, 17/06, 27/02, 35/00		
Applicant MITSUBISHI PHARMA CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 26 December 2003 (26.12.2003)	Date of completion of this report 30 April 2004 (30.04.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/006988

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 23-24

because:

☒ the said international application, or the said claims Nos. 23-24 relate to the following subject matter which does not require an international preliminary examination *(specify):*

SEE SUPPLEMENTAL SHEET

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 23-24 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

The inventions set forth in claims 23 and 24 correspond to "methods for the treatment of the human body by therapy" (PCT Rule 67.1(iv)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-22, 25-26	NO
Inventive step (IS)	Claims		YES
	Claims	1-22, 25-26	NO
Industrial applicability (IA)	Claims	1-22, 25-26	YES
	Claims		NO

2. Citations and explanations

The following documents were cited in the international search report.

Document 1: WO 99/35146 A1 (Glaxo Group, Ltd.)
Document 2: WO 00/31048 A1 (Warnar-Lambert Co.)

Document 1 indicates that compounds which are identical to the compounds represented by general formula (I) set forth in claim 15 of the present international application exhibit an action whereby they inhibit the expression of erbB-2 and/or EGFR, and that the compounds can be used to treat cancer and psoriasis by means of this action.

Therefore, the inventions set forth in claims 1-22 and 25-26 of the present international application lack novelty and do not involve an inventive step in the light of document 1.

Document 2 indicates that compounds which are identical to the compounds represented by general formula (I) set forth in claim 15 of the present international application exhibit an action whereby they inhibit the expression of erbB-2 and/or EGFR, and that the compounds can be used to treat cancer, arteriosclerosis and psoriasis by means of this action.

Therefore, the inventions set forth in claims 1-22 and 25-26 of the present international application lack novelty and do not involve an inventive step in the light of document 2.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-14, 18-22 and 25-26 pertain to compositions which comprise compounds that are defined by means of a desired characteristic, i.e. exhibiting a "Her2 and/or EGFR inhibiting" activity, as an active component. These claims include all compounds that exhibit such a characteristic; however, only a very small number of the claimed compounds are considered to be supported by the description as stipulated in PCT Article 6 or disclosed as stipulated in PCT Article 5.

Furthermore, with regards to "Her2 and/or EGFR inhibitors," it is impossible to specify the scope of compounds that exhibit such a characteristic in the light of common technical knowledge at the time of filing; therefore, these claims do not conform to the requirement of clarity as stipulated in PCT Article 6.